

Applicants: Debra M. Eckert, David C. Chan, Vladimir Malashkevich, Peter A. Carr and Peter S. Kim

Group: 1614

Examiner: Not Assigned

For: Inhibitors of HIV Membrane Fusion

## INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:  
This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)  
Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references are enclosed. (References AA-AE, AL-AL2, AR-AZ, AR2-AZ2, AR3-AZ3, AR4-AZ4, AR5-AZ5, AR6-AZ6, AR7-AZ7, AR8-AZ8, AR9-AW9)
- ☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☐ the enclosed English language abstract.
- ☒ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

U.S. Patent Application No. 09/484,925 by David C. Chan, Deborah Fass, Min Liu,  
James M. Berger and Peter S. Kim, filed January 18, 2000, Docket No.: 0399.1167-005.

U.S. Patent Application No. 09/364,497 by Debra M. Eckert, David C. Chan, Vladimir N. Malashkevich, Peter A. Carr and Peter S. Kim, filed July 30, 1999, Docket No.: 0399.1192-004.

U.S. Patent Application No. 09/668,072, by Debra M. Eckert, Tara R. Suntoke and Peter S. Kim, filed September 22, 2000, Docket No.: 0399.1192-007.

U.S. Patent Application No. 09/738,945, by Michael J. Root, Michael S. Kay, David C. Chan and Peter S. Kim, filed December 15, 2000, Docket No.: 0399.2002-002

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Examiner

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Date

- ☒ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

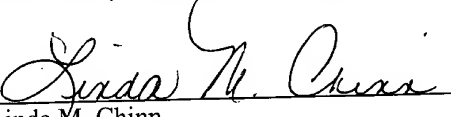
Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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INFORMATION DISCLOSURE CITATION  
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(Include additional sheets if necessary)

ATTORNEY DOCKET NO.  
0399.1192-008

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09/746,74

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
AA	5,444,044	8/22/95	Jiang et al.	514	12	3/26/92
AB	5,464,933	11/7/95	Bolognesi et al.	530	324	6/7/93
AC	5,656,480	8/12/97	Wild et al.	435	325	1/27/95
AD	5,840,843	11/24/98	Jiang et al.	530	350	6/7/95
AE	6,150,088	11/21/00	Chan et al.	435	5	4/17/98

FOREIGN PATENT DOCUMENTS

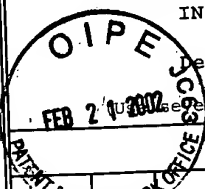
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
AL	WO 94/02505	03 Feb 94	PCT			
AM	WO 96/40191	19 Dec 96	PCT			
AN	WO 98/32848A	30 July 98	PCT			
AO	WO 00/06599	10 Feb 00	PCT			
AP	WO 00/40616	13 July 00	PCT			
AQ	WO 01/03723A1	18 Jan 01	PCT			
AL2	WO 01/44286A2	21 June 01	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Baum, Rudy, "Virus-cell Fusion Targeted for Drug Development," C&EN (1996).
AS	Blacklow, Stephen C., et al., "A Trimeric Subdomain of the Simian Immunodeficiency Virus Envelope Glycoprotein," Biochemistry, 34(46):14955-14962 (1995).
AT	Blake, James and Li, Choh Hao, "Adrenocorticotropin. 47. Synthesis and Biological Activity of Adrenocorticotropic Peptides Modified at the Tryptophan Position," J. Medicinal Chem. 18(4):423-426 (1975).

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AV	Bullough, Per A. et al., "Structure of influenza haemagglutinin at the pH of membrane fusion," <i>Nature</i> 371:37-43 (1994).
AW	Caffrey, Michael et al., "Three-dimensional solution structure of the 44kDa ectodomain of SIV gp41," <i>EMBO J.</i> 17(16):4572-4584 (1998).
AX	Cao, Jie et al., "Effects of Amino Acid Changes in the Extracellular Domain of the Human Immunodeficiency Virus Type 1 gp41 Envelope Glycoprotein," <i>J. Virology</i> 67(5):2747-2755 (1993).
AY	Chabala, John C., "Solid-phase combinatorial chemistry and novel tagging methods for identifying leads," <i>Curr. Opin. Biotech.</i> 6:632-639 (1995).
AZ	Chakrabartty, Avijit et al., "Aromatic Side-Chain Contribution to Far-Ultraviolet Circular Dichroism of Helical Peptides and Its Effect on Measurement of Helix Propensities," <i>Biochemistry</i> 32:5560-5565 (1993).
AR2	Chambers, Philip, et al., "Heptad Repeat Sequences are Located Adjacent to Hydrophobic Regions in Several Types of Virus Fusion Glycoproteins," <i>Journal of General Virology</i> , 71:3075-3080 (1990).
AS2	Chan, David C., et al., "Evidence that a Prominent Cavity in the Coiled Coil of HIV Type I gp41 is an Attractive Drug Target," <i>Proc. Natl. Acad. Sci. USA</i> 95:15613-15617 (1998).
AT2	Chan, David C., et al., "Core Structure of gp41 from the HIV Envelope Glycoprotein," <i>Cell</i> 89:263-273 (1997).
AU2	Chan, David C. and Kim, Peter A., "HIV Entry and Its Inhibition," <i>Cell</i> 93:681-684 (1998).
AV2	Chen, Yee-Hsiung et al., "Determination of the Helix and $\beta$ Form of Proteins in Aqueous Solution by Circular Dichroism," <i>Biochemistry</i> 13(16):3350-3359 (1974).
AW2	Chen, Benjamin K. et al., "Distinct Modes of Human Immunodeficiency Virus Type 1 Proviral Latency Revealed by Superinfection of Nonproductively Infected Cell Lines with Recombinant Luciferase-Encoding Viruses," <i>J. Virology</i> 68(2):654-660 (1994).
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AR3	Delwart, Eric L., et al., "Retroviral Envelope Glycoproteins Contain a "Leucine Zipper"-like Repeat," <i>AIDS Research and Human Retroviruses</i> , 6(6):703-706 (1990).
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AT3	Dutch, Rebecca Ellis et al., "Paramyxovirus Fusion Protein: Characterization of the Core Trimer, a Rod-Shaped Complex with Helices in Anti-Parallel Orientation," <i>Virology</i> 254:147-159 (1999).
AU3	Eckert, Debra M., et al., "Inhibiting HIV-1 Entry: Discovery of D-Peptide Inhibitors that Target the gp41 Coiled-Coil Pocket," <i>Cell</i> 99:103-115 (1999).
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AW3	Eckhart, Leopold et al., "Immunogenic Presentation of a Conserved gp41 Epitope of Human Immunodeficiency Virus Type I on Recombinant Surface Antigen of Hepatitis B Virus," <i>J. Gen. Virol.</i> 77:2001-2008 (1996)
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AY3	Fass, Deborah et al., "Retrovirus envelop domain at 1.7 Å resolution," <i>Nature Structural Biology</i> 3(5):465-469 (1996).
AZ3	Fass, Deborah and Kim, Peter S., "Dissection of a retrovirus envelope protein reveals structural similarity to influenza hemagglutinin," <i>Current Biology</i> 5(12):1-7(1995).
AR4	Furuta et al., "Capture of an early fusion-active conformation of HIV-1 gp41," <i>Nature Structural Biology</i> 5(4):276-279 (1998).
AS4	Gallagher, William R., et al., "A General Model for the Transmembrane Proteins of HIV and Other Retroviruses," <i>Aids Research and Human Retroviruses</i> , 5(4):431-440 (1989).
AT4	Harbury, Pehr B. et al., "Repacking protein cores with backbone freedom: Structure prediction for coiled coils," <i>Proc. Natl. Acad. Sci. USA</i> 92:8408-8412 (1995).
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AW4	Hooft, Rob W.W. and Vriend, Gert, "Errors in protein structures," <i>Nature</i> 381:272 (1996).
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AZ4	Jiang, Shibo et al., "HIV-1 inhibition by a peptide," <i>Nature</i> 365:113 (1993).
AR5	Jones, T.A. et al., "Improved Methods for Building Protein Models in Electron Density Maps and the Location of Errors in these Models," <i>Acta Cryst.</i> A47:110-119 (1991).
AS5	Judice, J. Kevin et al., "Inhibition of HIV type 1 infectivity by constrained $\alpha$ -helical peptides: Implications for the viral fusion mechanism," <i>Proc. Natl. Acad. Sci. USA</i> 94:13426-13430 (1997).
AT5	Kilby, J. Michael et al., "Potent suppression of HIV-1 replication in humans by T-20, a peptide inhibitor of gp41-mediated virus entry," <i>Nature Medicine</i> 4(11):1302-1307 (1998).
AU5	Kliger, Yossef et al., "Mode of Action of an Antiviral Peptide from HIV-1," <i>J. Biol. Chem.</i> 276(2):1391-1397 (2001).
AV5	Kozarsky, Karen et al., "Glycosylation and Processing of the Human Immunodeficiency Virus Type 1 Envelope Protein," <i>J. Acquired Immune Deficiency Syndromes</i> 2:163-169 (1989).
AW5	Kubinyi, Hugo, "Combinatorial and computational approaches in structure-based drug design," <i>Curr. Op. In Drug Disc. &amp; Dev.</i> 1(1):16-22 (1998).
AX5	Kuntz, Irwin D., "Structure-Based Strategies for Drug Design and Discovery," <i>Science</i> 257:1078-1082 (1992 August).
AY5	LaCasse, Rachel A. et al., "Fusion-Competent Vaccines: Broad Neutralization of Primary Isolates of HIV," <i>Science</i> 283:357-362 (1999).
AZ5	Lam, Kit S. et al., "A new type of synthetic peptide library for identifying ligand-binding activity," <i>Nature</i> 354:82-84 (1991).
AR6	Lambert, D.M. et al., "Peptides from conserved regions of paramyxovirus fusion (F) proteins are potent inhibitors of viral fusion," <i>Proc. Natl. Acad. Sci. USA</i> 93:2186-2191 (1996).

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AS6	Letvin, Norman L., "Progress in the Development of an HIV-1 Vaccine," <i>Science</i> 280:1875-1880 (1998).
AT6	Li, Zhe, et al., "Anti-malarial Drug Development Using Models of Enzyme Structure," <i>Chemistry &amp; Biology</i> , 1:31-37 (1994).
AU6	Lu, Min, et al., "A Trimeric Structural Domain of the HIV-1 transmembrane glycoprotein," <i>Nature Structural Biology</i> , 2(12):1-8 (1995).
AV6	Lu, Min and Kim, Peter S., "A Trimeric Structural Subdomain of the HIV-1 Transmembrane Glycoprotein," <i>J. Biomol. Structure &amp; Dynamics</i> 15(3):465-471 (1997).
AW6	Malashkevich, Vladimir N. et al., "Crystal structure of the simian immunodeficiency virus (SIV) gp41 core: Conserved helical interactions underlie the broad inhibitory activity of gp41 peptides," <i>Proc. Natl. Acad. Sci. USA</i> 95:9134-9139 (1998).
AX6	Meng, Elaine C., et al., "Automated Docking with Grid-Based Energy Evaluation," <i>Journal of Computational Chemistry</i> , 13(4):505-524 (1992).
AY6	Muster, Thomas et al., "Cross-Neutralizing Activity against Divergent Human Immunodeficiency Virus Type 1 Isolates Induced by the gp41 Sequence ELDKWAS," <i>J. Virology</i> 68(6):4031-4034 (1994).
AZ6	Muster, Thomas et al., "A Conserved Neutralizing Epitope on gp41 of Human Immunodeficiency Virus Type 1," <i>J. Virology</i> 67(11):6642-6647 (1993).
AR7	Nautiyal, Shivani and Alber, Tom, "Crystal structure of a designed, thermostable, heterotrimeric coiled coil," <i>Protein Science</i> 8:84-90 (1999).
AS7	Nolte, Alexis et al., "Mirror-design of L-oligonucleotide ligands binding to L-arginine," <i>Nature Biotechnology</i> 4:1116-1119 (1996).
AT7	O'Neil, Karyn T. and DeGrado, William F., "A Thermodynamic Scale for the Helix-Forming Tendencies of the Commonly Occurring Amino Acids," <i>Science</i> 250:646-351 (1990).
AU7	Purtscher, Martin et al., "Restricted antigenic variability of the epitope recognized by the neutralizing gp41 antibody 2F5," <i>AIDS</i> 10:587-593 (1996).
AV7	Reimann, Keith A. et al., "A Chimeric Simian/Human Immunodeficiency Virus Expressing a Primary Patient Human Immunodeficiency Virus Type 1 Isolate env Causes an AIDS-Like Disease after In Vivo Passage in Rhesus Monkeys," <i>J. Virology</i> 70(10):6922-6928 (1996).

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AW7	Richman, Douglas D., "Nailing down another HIV target," <i>Nature Medicine</i> 4(11):1232-1233 (1998).
AX7	Rimsky, Laurence T. et al., "Determinants of Human Immunodeficiency Virus Type 1 Resistance to gp41-Derived Inhibitory Peptides," <i>J. Virology</i> 72(2):986-993 (1998).
AY7	Ring, Christine S., et al., "Structure-based Inhibitor Design by Using Protein Models for the Development of Antiparasitic Agents," <i>Proc. Natl. Acad. Sci. USA</i> , 90:3583-3587 (1993).
AZ7	Root, Michael J. et al., "Protein Design of an HIV-1 Entry Inhibitor," <i>Science</i> 291:884-888 (2001).
AR8	Schumacher, Ton N.M. et al., "Identification of D-Peptide Ligands Through Mirror-Image Phage Display," <i>Science</i> 271:1854-1857 (1996).
AS8	Shuker, Suzanne B. et al., "Discovering High-Affinity Ligands for Proteins: SAR by NMR," <i>Science</i> 274:1531-1534 (1996).
AT8	Singh, Mona et al., "LearnCoil-VMF: Computational Evidence for Coiled-coil-like Motifs in Many Viral Membrane-fusion Proteins," <i>J. Mol. Biol.</i> 290:1031-1041 (1999).
AU8	Tan, Kemin et al., "Atomic structure of a thermostable subdomain of HIV-1 gp41," <i>Proc. Natl. Acad. Sci. USA</i> 94:12303-12308 (1997).
AV8	Tarrago-Litvak, Laura et al., "The reverse transcriptase of HIV-1: from enzymology to therapeutic intervention," <i>FASEB J.</i> 8:497-503 (1994).
AW8	Tucker, Thomas J. et al., "Development of Nonnucleoside HIV Reverse Transcriptase Inhibitors," <i>Methods in Enzymology</i> 275:440-472 (1996).
AX8	Tyagi, Sanjay et al., "Multicolor molecular beacons for allele discrimination," <i>Nature Biotechnology</i> 16:49-53 (1998).
AY8	Weissenhorn, Winfried et al., "Assembly of a rod-shaped chimera of a trimeric GCN4 zipper and the HIV-1 gp41 ectodomain expressed in <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 94:6065-6069 (1997).
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AR9	Weissenhorn, Winfried et al., "Crystal Structure of the Ebola Virus Membrane Fusion Subunit, GP2, from the Envelope Glycoprotein Ectodomain," <i>Molecular Cell</i> 2:605-616 (1998).
AS9	Wild, Carl et al., "A synthetic peptide inhibitor of human immunodeficiency virus replication: Correlation between solution structure and viral inhibition," <i>Proc. Natl. Acad. Sci. USA</i> 89:10537-10541 (1992).

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<p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p>December 31, 2001</p> <p>(Use several sheets if necessary)</p>		APPLICANT Debra M. Eckert et al.	
		FILING DATE December 21, 2000	GROUP 1614
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	AT9	Wild, Carl T. et al., "Peptides corresponding to a predictive $\alpha$ -helical domain of human immunodeficiency virus type 1 gp41 are potent inhibitors of virus infection," <i>Proc. Natl. Acad. Sci. USA</i> 91:9770-9774 (1994).	
	AU9	Williams, Kelly P. et al., "Bioactive and nuclease-resistant l-DNA ligand of vasopressin," <i>Proc. Natl. Acad. Sci. USA</i> 94:11285-11290 (1997).	
	AV9	Youngquist, R. Scott et al., "Generation and Screening of Combinatorial Peptide Libraries Designed for Rapid Sequencing by Mass Spectrometry," <i>J. Am. Chem. Soc.</i> 117:3900-3906 (1995).	
	AW9	Malashkevich, Vladimir N. et al., "Core structure of the envelope glycoprotein GP2 from Ebola virus at 1.9-Å resolution," <i>Proc. Natl. Acad. Sci. USA</i> 96:2662-2667 (1999).	
EXAMINER		DATE CONSIDERED	

